REMARKS

Applicants have carefully reviewed and considered the Office Action mailed on October 14, 2004 and the documents cited therewith.

Claim 1 is amended, claims 4-13, 16-18, and 20-27 were canceled previously, and no claims are added; as a result, claims 1-3, 14, 15, 19, and 28-32 are now pending in this application.

Claim 1 has been amended to insert the phrase *forms a solid implant in which the biologically active mixture is entrapped when the controlled release formulation contacts an aqueous medium or body fluid.* This amendment was made in order to conform the claim to the specification as filed and not in view of the Examiner's rejection. Support for this amendment to claim 1 appears *inter alia* at page 4, lines 25-28 of Applicants' specification. Accordingly, the scope of equivalents of claim 1 is believed to be unaffected.

Personal Interview

Applicant wishes to thank the Examiner for extending the courtesy of a personal interview to Applicant's representative, Richard A. Schwartz, on December 2, 2004.

Applicant's representative noted that the content of the phrase *is used to form an in situ solid implant* in claim 1 as previously presented is a novel aspect of Applicant's invention, and suggested to the Examiner the replacement language *forms a solid implant in which the biologically active mixture is entrapped when the controlled release formulation contacts an aqueous medium or body fluid* for the phrase. The Examiner agreed that the suggested phrase was not a use limitation; as such, the phrase is given patentable weight.

This account is believed to be a complete and accurate summary of the interview as required by 37 C.F.R. § 1.133. If the Examiner believes that this summary is inaccurate or incomplete, Applicants respectfully request that the Examiner point out any deficiencies in his next communication so that Applicants can amend or supplement the interview summary.

Documents Missing from the USPTO File

The Examiner has noted that the documents corresponding to the PTO Form 1449 supplied with Applicant's response filed July 6, 2004 are not of record. These documents were provided to the Office as part of the Information Disclosure Statement filed August 5, 1998. A duplicate copy of the documents is provided herewith for the convenience of the Examiner.

Objection to Claims Under 37 C.F.R. § 1.75(c)

Dependent claims 28 and 32 were objected to under 37 CFR § 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. The Examiner considers that claims 28 and 32 broaden independent claim 1, from which they depend, by adding essential ingredients to the composition. Office Action at page 3. Reconsideration of this objection is respectfully requested.

Claim 1 recites that the biologically active mixture consists essentially of the biologically active agent and a pharmaceutically acceptable, aqueous medium as a protective carrier. The transitional phrase *consisting essentially of* limits the scope of a claim to the specified materials or steps and "and those that do not affect the basic and novel characteristics(s)" of the claimed invention. MPEP § 2111.03 (quoting *In re Herz*, 573 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976)(emphasis in original). The *Herz* court held that appellants' claims did not exclude the prior art dispersant, because appellants specification indicated the claimed composition could contain any well-known additive, such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. *Ibid.*

Similarly, there is no evidence in this application to indicate that the additional components recited in claim 32 could affect the characteristic of the protective carrier that permits it to act as a protective carrier. As such, claim 1 can be viewed as including the subject matter of claim 32, and therefore claim 32 does not broaden claim 1.

Contrariwise, claim 1 twice recites the open transitional term *comprising*, once directly after the preamble and once in the phrase *the controlled release formulation comprising a pharmaceutically acceptable, biodegradable thermoplastic polymer*. As such the composition of

claim 1 is open to the inclusion of unnamed components, and therefore claim 28 does not broaden claim 1.

Withdrawal of this objection is respectfully requested.

Rejection of the Claims under 35 U.S.C. § 112, first paragraph

1. New matter rejection

Claim 28 was rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement. The Examiner stated that Applicant has not disclosed a mixture of polymeric and non-polymeric materials in the organic phase; the Examiner is of the opinion that the two materials are disclosed only in the alternative. This rejection is respectfully traversed.

Applicant would like to draw the attention of the Examiner to the penultimate sentence of the Abstract, which reads: *The matrix forming material can be a polymeric material, a non-polymeric material or a combination of both.* (emphasis added). This sentence provides clear descriptive support for the subject matter of claim 28. The abstract of the disclosure has been interpreted to be a part of the specification for the purpose of compliance with 35 U.S.C. § 112, first paragraph. MPEP § 608.01(b)(citing *In re Armbruster*, 512 F.2d 676, 678-79, 185 USPQ 152, 154 (CCPA 1975). Withdrawal of this part of the rejection is respectfully requested.

2. Scope of enablement rejection

Claim 28 was rejected under 35 USC § 112, first paragraph, because the specification, while being enabling for lipids, allegedly does not reasonably provide enablement (how to make) for any non-polymeric material, such as a salt. The Examiner pointed to page 20, lines 21 *et seq* for "a list of substantially water-insoluble compounds that may broadly be characterized as lipids. No other class of compounds is specified." This rejection is respectfully traversed.

Applicant assumes the Examiner intended to draw attention to page 10, line 21 where the disclosure of suitable non-polymeric materials begins; page 20, line 21 *et seq* is beyond the end of Applicant's specification. If this assumption is correct, the Examiner is saying that Applicant's comprehensive disclosure of suitable non-polymeric materials is enabled.

Applicant expects that during examination the Examiner will not read limitations into the claims, but that he will give the pending claims the broadest reasonable interpretation consistent with the specification. MPEP § 2173.05(a)(emphasis added). Claim 28 is not read in a vacuum, but rather in light of the specification.

Applicant discloses that the non-polymeric material must be matrix forming. Specification at page 9, lines 5-6. One would interpret the meaning of *non-polymeric* in claim 28 accordingly. Therefore, Applicant should not be required to provide enablement for subject matter that is not part of his invention, i.e. for non-polymeric materials that do not form a matrix.

Withdrawal of this part of the rejection is respectfully requested.

§102 Rejections of the Claims

Claims 1-3, 14-15, 19, and 29-32 were rejected under 35 USC § 102(b) as being anticipated by Yamamoto et al. (USP 4,954,298). The Examiner stated: "Yamamoto et al teach a W/O emulsion composed of a water soluble drug containing solution as the inner aqueous phase and a polymer containing solution as the oil phase (abstract)." Office Action at page 2. This rejection is respectfully traversed.

Claims 1-3, 14, 15, 19, and 29-32 were rejected under 35 USC § 102(b) as being anticipated by Okada et al. (USP 4,652,441). The Examiner stated: "Okada et al teach water-oil emulsions comprising a water soluble drug in the aqueous phase and a polymer in the oil phase (abstract).... An intended use is not considered a patentable limitation during prosecution before the USPTO." Office Action at pages 2-3.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989). To constitute anticipation, the claimed subject matter must be identically disclosed in the prior art. *In re Arkley*, 172 U.S.P.Q. 524 at 526 (C.C.P.A. 1972). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 101

(Fed. Cir. 1991). To overcome the defense of anticipation, "it is only necessary for the patentee to show some tangible difference between the invention and the prior art." *Del Mar Engineering Lab v. Physio-Tronics, Inc.*, 642 F.2d 1167, 1172, (9th Cir. 1981).

The W/O emulsions of Yamamoto et al. are used to prepare sustained-release microcapsules containing a water-soluble drug. The microcapsules can be administered to a host, such as by implantation as such or by injection of a dispersion of the microcapsules. Yamamoto et al. at column 8, lines 12-27. In addition, the W/O emulsion is added to a third, aqueous phase and emulsified into a W/O/W triplicate-phase emulsion. The W/O/W emulsion is then subjected to in-water drying and solvent removal to produce the microcapsules. Yamamoto et al. at column 6, lines 20-25.

In contrast, Applicant's emulsion of a biologically active mixture and a controlled release formulation forms an implant *in situ* when contacted with an aqueous medium or a body fluid. That the W/O emulsions of Yamamoto et al. are not the same as those of Applicant's is evident from the fact that the Yamamoto et al. emulsions do not solidify when added to the third, aqueous phase or when subjected to in-water drying. Further, the microcapsules of Yamamoto et al. may be implanted after they are formed; in contrast Applicant's emulsion forms a solid implant *in situ* after delivery to the implant site. Therefore, because the claimed subject matter is not identically disclosed in Yamamoto et al., there can be no anticipation. Withdrawal of this rejection is respectfully requested.

Similarly, the W/O emulsion of Okada et al. is also added to a third, aqueous layer and emulsified into a W/O/W ternary layer emulsion, which is then subjected to in-water drying and solvent removal to produce microcapsules. Okada et al. at column 7, lines 51-55. The microcapsules can be administered to a host, such as by injection of a dispersion of the microcapsules in an aqueous vehicle, or as fine granules. Okada et al. at column 8, line 58 to column 9, line 10.

In contrast, Applicant's emulsion of a biologically active mixture and a controlled release formulation forms an implant *in situ* when contacted with an aqueous medium or a body fluid. That the W/O emulsions of Okada et al. are not the same as those of Applicant's is evident from the fact that the Okada et al. emulsions do not solidify when added to the third, aqueous phase or when subjected to in-water drying. Further the emulsions of Okada et al. do not form a

solid implant *in situ* after delivery to the implant site. The formation of a solid implant is not an intended use, but rather is a recitation of the mode of operation of the composition, which mode is brought about by virtue of the constitution of the composition. Therefore, because the claimed subject matter is not identically disclosed in Okada et al., there can be no anticipation. Withdrawal of this rejection is respectfully requested.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (703) 239-9592 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

RICHARD L. DUNN

By his Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(703) 239-9592

Date 1/14/05

By _____
Richard A. Schwartz
Reg. No. 48,105

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 14th day of January, 2005.

Dawn M. Poole
Name

Dawn M. Poole
Signature